

Appl. No. 10/533,749
Amdt. Dated May 21, 2008
Reply to Office Action of December 21, 2007

Amendments to the Specification:

Please replace paragraph [0006] with the following amended paragraph:

[0006] To flush the lock system and its fluid connected catheter lumen, sterile saline or other flush solution is commonly aspirated from a multi-dose vial. Since, at the present time, most drug vials have elastomeric septae intended for receiving a sharp needle, this aspiration procedure often requires a disposable adapter to prevent needle sticks, which adds to the general cost of the lock procedure. A simple saline flush also requires a sterile syringe and, with some systems, a sterile cannula connected with the syringe, each further adding to the expense. Because multi-dose vials carry the risk of cross contamination if not managed properly and because time dependent personnel costs are progressively rising in hospitals, an alternative, pre-filled disposable saline flush syringes are being offered by corporations. However the storage of sterile flush solution within individually packaged syringes is also expensive, and such devices can cost in excess of \$.50 for a single unit. There are hundreds of millions of such procedures performed in the US each year so that, considering all related costs, the expense of maintaining locks in the US alone probably exceeds several ~~100s~~ hundreds of millions of dollars.

Please replace paragraph [0017] with the following amended paragraph:

[0017] In one embodiment the system includes a single tube for mounting with a patient, the tube has a distal end connectable to the catheter and at least one proximal end with a terminal for intermittent connection with a source of flush solution. The terminal includes a seal for sealing the proximal end of the tube when the source of flush solution is disconnected from the terminal. The tube further defines an internal open space defining a an internal volume which is reducible, and a lumen extending through from the sealed proximal terminal to the distal end, so that when a source of flush solution is connected to the terminal, flush solution can enter the tube from the fluid source through the terminal and flow through the lumen to at least partially fill the internal space. The lumen defines at least a portion of the internal volume. The system further includes a volume reducer comprised of at least one volume-reducing element. The volume reducer is sized and configured to sequentially reduce the internal volume of the tube at a plurality of different times after the distal end has been connected with the catheter, the flush solution has been flowed into the space from the source, and the source has been disconnected from the terminal. In one embodiment the tube is elongated and has different diameters along its length.

Please replace paragraph [0039] with the following amended paragraph:

[0039] FIG. 6 shows an embodiment of a catheter-flushing clamp in its closed position. This figure illustrates that, according to the present invention, the displacement volume of

the catheter flush generation system ~~100s~~ 100 and 200 are set by the compressed length 260 and the diameter of the segment of the tubing 104 or 204 along the compressed length 260. (If compression elevations are provided as in FIG. 5 some fluid may be trapped between these elevations so that the compression length 260 can be slightly increased.) According to the present invention, the internal diameter of the tubing 104 and the compressed length 260 are selected to achieve the desired range of volumes of displaced catheter flushing fluid.

Please replace paragraph [0040] with the following amended paragraph:

[0040] In operation, first the catheter flush generation system 200 and catheter 230 have been filled with fluid injected through the distal terminal 206. Then the locking arm 214 is deflected downward into a closed position compressing tubing 204 between compressing surfaces and the locking ~~the~~ arm in the locked position under the latch 225. As shown in FIG. 5, the proximal portion of the compressing surface can have a projecting member ~~208~~ 270, which, during closure, promptly occludes the proximal portion of tubing 204 thereby propelling the fluid volume within tube 204 distally toward the catheter as the arm 214 is further deflected into the locked position. The compressing surface can be flat or (as shown in FIG. 6) can be comprised of sequential elevations (as in FIG. 5), or it can be convex or concave longitudinally. Once the clamp has been latched, according to the a preferred embodiment of the present invention, additional

force applied to achieve additional compression of the clamp will not further displace additional fluid so that rebound of fluid back into the catheter does not occur when the thumb pressure is released. In some embodiments (as in FIG. 6), when the arm is held in position by the latch, a uniform distance is provided between the distal face of the upper compressive surface and opposing lower surface, matched to the width of the tube when the tube has a completely compressed lumen, so that, when force applied to the top of the clamp is released after latching, complete compression of the lumen is maintained such that the lumen does not enlarge to induce negative pressure causing reflux of fluid back toward the clamp. If preferred, greater flexibility in the distance between compressing surfaces can be provided by providing a distal elevation 280 (FIG. 5) at the distal end of one or both of the compressing surfaces to assure compression is complete.

Please replace paragraph [0041] with the following amended paragraph:

[0041] A presently preferred embodiment of the sequential catheter-flushing fluid lock system according to the present invention, which can substantially reduce the need to routinely access fluid lock systems, is shown in FIG. 7. Three low profile, catheter-flushing clamps 401, 402, and ~~404~~ 403 are mounted in a series upon tubing 404. Tubing 404 has enlarged portion 405 and closed proximal terminal 406 (shown as a luer receiving valve) and a distal luer terminal 108, for connection with a catheter 409 at catheter hub 410. The catheter 409 has an internal lumen 411 defining a length shown as

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414. These catheter-flushing clamps 401,402 and ~~404~~ 403 are marked at both the top (thumb contact) surface ~~415~~ 115 and the bottom surface with "1st, 2nd, and 3rd" to remind the nurse of the order of closure every 8 hours as will be discussed. The tubing 404 preferably has a generous internal diameter (for example in the range of 4-6 mm) so that the flush volume generated by each catheter-flushing clamp is relatively high in comparison to the volume of the lumen 411 along length 414. In one example, a catheter-flushing clamp of the type for example shown in FIGS. 2-4 with a compression length of 9 mm mounted on tubing with a internal diameter of about 3.5-4 mm, can generate a flush volume exceeding the entire internal volume of the potential indwelling length 414 of a typical 1.5 inch 18 gauge catheter (as for example[,] the "Insyte" catheter marketed by Becton Dickinson), so that the sequential closure of each of the three such flushing clamps 401,402,403, can achieve complete flushing of the lumen 411 of catheter 409 on three separate occasions without requiring the opening or internal access of the system 400. Yet the volume of the flush is low, predetermined, and discrete so as to minimize the amount of flush solution displaced into the patient's systemic system.

Please replace paragraph [0042] with the following amended paragraph:

[0042] In operation of the sequential catheter flush system 400; the nurse connects the system to catheter hub 410 (if it is not pre-connected or integral with the catheter). The

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nurse then flushes ("charges") the system. If the proximal terminal is not a positive pressure valve or if the valve is simply threaded rather than permanently attached, the first (most proximal) clamp 401 is closed. After this, if no medication has been infused in the interim, each sequential clamp (402 then 403) is closed at 8 hr. intervals to flush the catheter 409 every shift (this interval may be prolonged with specialized formulations as discussed previously). After 24 hours, or eight hours after the last catheter-flushing clamp has been closed, all the catheter-flushing clamps are opened and the system 400 is "recharged" by flushing the system 400 with saline through the proximal terminal 406. The system 400 is now ready to provide another 24 hours of sequential catheter flush. Accordingly one method for intermittently flushing the catheter comprises steps of reducing the internal volume of the extension tube after a first delay, a second delay, and a third delay where the first residual volume is less than initial volume, the second residual volume is less than the first residual volume. The method can maintain the catheter for 24 hrs and can be repeated for another 24 hours.

Please replace paragraph [0043] with the following amended paragraph:

[0043] When this new method is applied to maintain patency of an indwelling catheter, external flushing need only be applied every 24 hours or even less frequently, greatly reducing cost and the number of times the system is opened and potentially reducing the

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infection risk. Deployment of the sequential catheter flush system could, over several years; save a hospital hundreds of thousands of dollars while at the same time reducing nurse workload and patient and nurse infection risk. In many cases the patient may be receiving medication (such as an antibiotic) only every 24 hours, or the protocol (such as may be applied with PICC catheters) may call for flushing only every 12 to 24 hours so that the sequential reducing of volume every 24 hours up to 3 times can provide a method for maintaining the patency of an indwelling catheter over a 24-72 hour period. For these reasons, the sequential catheter flush system according to the present invention can with some patients, eliminate all flushes other than those delivered immediately after antibiotic infusion. Failure rates of lock devices due to delayed or missed flushes may also be minimized by the present invention since the sequential catheter flush system is more easily applied and less time consuming.